K002053

AUG 3 2000

Summary of Safety and Effectiveness
Navitrack™ System – Optical Passive Option

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and CFR § 807.92.

A. SUBMITTER INFORMATION

1. Company Name :	ORTHOsoft Inc.
2. Company Address :	80 Queen street, suite 604 Montreal, Quebec Canada, H3C 2N5
3. Company Phone :	(514)-861-4074
4. Contact Person :	Nicole Landreville, B.Eng. Regulatory Affairs and Quality Assurance Manager ORTHOsoft Inc.
5. Date Summary Prepared:	June 23rd, 2000

B. DEVICE IDENTIFICATION

1. Proprietary Name :	Navitrack™ System – Optical Option
2. Classification Name :	Stereotaxic Instrument (84 HAW) ; 21 CFR § 882.4560

C. DEVICE UPDATE

This submission describes updates made to the Navitrack™ System to include the option of optically tracking surgical instruments via an industry standard infra-red LED based camera system and the use of reflection of infrared light off of reflective spheres on the instruments, and/or the use of active led tracker emitting light being captured by the camera.

D. DEVICE DESCRIPTION

The **indications for use** for the Navitrack™ System – Optical Option have not changed and are as follow:

> The Navitrack™ System is a stereotaxic instrument indicated for use in precisely positioning instruments or implants during orthopedics surgery, such as operation perform within spinal structures.

The **intended use** for the Navitrack™ System – Optical Option has not changed and is as follows:

K002053

The Navitrack™ System is a stereotaxic instrument indicated for use in precisely positioning instruments or implants during orthopedic surgery, such as operation performed within spinal structures.

The Navitrack™ System enables the surgeon to review radiology images from different modalities in two-dimensional and three-dimensional display. This system also enables the surgeon to virtually manipulate bone structures as reconstructed from these modalities in order to perform pre-operative planning.

E. FUNDAMENTAL SCIENTIFIC TECHNOLOGY

The fundamental scientific technology of the modified device has not changed. The software, the design and the method of manufacture have not change. The energy type of the position tracking system changed from magnetic to optical. However, the optical position-tracking device has been used in other legally marketed devices within the same classification regulation for the same intended use.

Technical differences that exist between these two types of position tracking systems do not affect the relative safety or effectiveness of the Navitrack™ System – Optical Option.

F. SPECIAL PREMARKET NOTIFICATION 510(k) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Special Premarket Notification 510(k) Reviewer's Checklist is provided at the beginning of this submission.

G. CONCLUSION

The Navitrack™ System – Optical Option was shown to be substantially equivalent to the original Navitrack™ System with Magnetic Tracking System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 2000

Ms. Nicole Landreville, B. Eng.
Regulatory Affairs and
Quality Assurance Manager
Orthosoft, Inc.
80 Queen Street, Suite 604
Montreal, Quebec,
Canada

Re: K002053
Trade Name: Navitrak ™ System - Optical Option
Regulatory Class: II
Product Code: HAW
Dated: July 5, 2000
Received: July 6, 2000

Dear Ms. Landreville:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number : K002053

Device Name: Navitrack ™ System – Optical Option

Indications for Use: The Navitrack ™ System is a stereotaxic instrument indicated for use in precisely positioning instruments or implants during orthopedics surgery, such as operation perform within spinal structures.

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Dianne R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002053

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)